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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,887	07/24/2003	David J. Lentz	11350.5	1036

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EXAMINER	
LEUNG, RICHARD L	

ART UNIT	PAPER NUMBER
3744	

DATE MAILED: 08/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,887	LENTZ ET AL.	
	Examiner	Art Unit	
	Richard L. Leung	3744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *2,9,14 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the term "p_t" recited on lines 1 and 2 of page 6 of the specification is understood to be -- t_t --. Appropriate correction is required.

Claim Objections

2. Claim 2 is objected to because of the following informalities: the limitation that the length of the supply tube is less than or equal to the length of the capillary tube as recited in the last line of the claim is unsupported by the specification, which describes the opposite relationship on page 7, lines 15-16. It is suggested that the phrase "less than" as recited on the last line of the claim be changed to --greater than-- in order to be in agreement with the disclosure. Appropriate correction is required.

3. Claims 9, 14, and 20 are objected to because of the following informalities: the recitations of the term "p_t" in the claims are understood to be -- t_t --. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, for lack of antecedent basis in the specification. The limitation that the length of the supply tube is less than or equal to the length of the capillary tube as recited in the last line of the claim is

unsupported by the specification, which describes the opposite relationship on page 7, lines 15-16. It is suggested that the phrase "less than" as recited on the last line of the claim be changed to --greater than-- in order to adhere to the disclosure, and the claim shall be treated as such, in light of the specification, for the remainder of this action. However, appropriate correction is still required to overcome this rejection.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 10-12, 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Dobak, III (US-5957963). Dobak, III discloses a heat transfer system for use in performing hypothermia of a selected biological tissue comprising a hollow supply tube 20 having a proximal end and a distal end, a capillary tube 22 having a proximal end and a distal end with the proximal end thereof connected in fluid communication with the distal end of said supply tube 20, said capillary tube 22 being formed with a lumen inherently having a length and a diameter. Also disclosed is a tip member 26 positioned to surround the distal end of said capillary tube to create a cryo-chamber therebetween and a source of refrigerant fluid, refrigeration compressor unit 12, connected in fluid communication with the proximal end of the supply tube 20 to introduce the refrigerant fluid into the supply tube 20 inherently at a working pressure for the transfer of the refrigerant fluid through said supply tube 20 and through said

capillary tube 22 for exit from the distal end of said capillary tube 22 and into said cry-chamber in a substantially liquid state for transition of the refrigerant fluid into a gaseous state inherently with a tip pressure and a tip temperature for heat transfer through said tip member 26 and into the gaseous fluid refrigerant in said cryo-chamber (see column 7, lines 1-8), as required by claim 1. The lumen of said supply tube 20 has a diameter of about 0.75 millimeters and a length of 70 to 100 centimeters (column 6, lines 25-32). The lumen of said capillary tube 22 has a diameter of about 0.25 millimeter or approximately 0.0098 inch (column 6, lines 49-51), and a length of 15 to 25 centimeters (column 6, lines 43-44). Therefore the diameter and length of the lumen of said capillary tube 22 are less than the diameter and length of the lumen of said supply tube 20, as required by claim 2. The aspect ratio of the diameter of the lumen of said capillary tube 22 to the length of the lumen of said capillary tube 22 is 0.25 millimeter to 25 centimeters, which is equivalent to 0.0010 and is within the range of 0.0008 to 0.0017 as required by claim 3. The length of said capillary tube 22 can range from 15 to 25 centimeters, as already stated above, which is equivalent to about 5.91 inches to 9.84 inches. Therefore the length of said capillary tube 22 is in a range between approximately 4.5 inches and approximately 10 inches as required by claim 4.

8. It is revealed in the specification of the present invention, as required for claim 10, that the means for providing a liquid refrigerant at a first pressure consists of any type of pressure vessel known in the pertinent art (page 6, lines 25-26), that the means for reducing the pressure on the liquid refrigerant from a first pressure to a second pressure consists of flowing the liquid refrigerant through a capillary tube (page 9, lines

8-10), and that the means for introducing the liquid refrigerant into a cryo-chamber for the transition of the liquid refrigerant into a gaseous state in the cryo-chamber to cause heat transfer from the outside of the cryo-chamber into the cryo-chamber consists of having the liquid refrigerant exit said capillary tube and expand into said cryo-chamber (page 9, lines 23-24). It should be evident from the above discussion of claim 1 that all the limitations set forth by claim 10 are met by Dobak, III, because the refrigeration compressor unit 12 equivalent to a pressure vessel, a capillary tube 22 is used to reduce the pressure of the liquid refrigerant, and the liquid refrigerant is expanded in a cryo-chamber upon exiting said capillary tube 22, allowing for the heat transfer into said cryo-chamber from the outside. Furthermore, it should be evident from the above discussion of claims 1, 3, and 4 that the requirements of claims 11 and 12 are also met.

9. In addition to disclosing a heat transfer system, Dobak, III also discloses a method for transferring heat which comprises the steps of providing a liquid refrigerant at a first pressure, using refrigeration compressor unit 12, reducing the pressure on the liquid refrigerant from a first pressure to a second pressure by advancing the liquid refrigerant though a hollow supply tube 20 to a capillary tube 22 having a proximal end and a distal end, and introducing the liquid refrigerant into a cryo-chamber at the second pressure for transition of the liquid refrigerant into a gaseous state in the cryo-chamber to cause transfer of heat outside the cryo-chamber into the cryo-chamber (see column 7, lines 1-8), as required by claim 16. As already discussed above, said capillary tube 22 has a length within a range of approximately 4.5 inches to approximately 10 inches and a diameter of said capillary tube is .25 millimeters and is therefore in a range

between approximately 0.008 inch and approximately 0.010 inch. The aspect ratio of the diameter and length of the lumen of said capillary tube 22 is within a range of 0.0008 to 0.0017, also discussed above. Therefore, the requirements of claims 17 and 18 are met.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III (US-5957963). Claim 5, in addition to claim 4, which is already treated above, requires that the diameter of said capillary tube be 0.008 inch. Dobak, III discloses a heat transfer system with a capillary tube 22 of inner diameter 0.25 millimeters (column 6, line 49-51), which is approximately equal to 0.0098 inch. However, the specific size given by Dobak, III is approximate and does not appear critical. It is stated in column 6, line 48-51 that the size given is applicable for use in internal carotid artery applications. Although there is obviously an upper size limit for the diameter size since the device must fit in the artery, there is no reason why the diameter of said capillary tube 22 could not be reduced, so long as refrigerant can still flow through it. Therefore, it would have been obvious to one of ordinary skill in the art to decrease the diameter of the capillary tube 22 of Dobak, III to 0.008 inch because such a modification would have involved a mere change in the size of a component, the smaller size is still capable of functioning

in the carotid artery, and the smaller size would even allow the heat transfer device to fit more easily into the carotid artery. Alternatively, it is not sufficiently shown in the disclosure of the present invention that a capillary diameter of exactly 0.008 inch is critical over the diameter given by Dobak, III. This is further evidenced by the recitation of lines 23-24 of page 5 in the specification that states the diameter of the capillary tube is "between about 0.008 inches and 0.010 inches." Therefore the claim would have been obvious over Dobak, III since a diameter of 0.25 millimeters falls within the understandable scope of the present invention.

12. Claim 1-4 and 6-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lalonde et al. (US-6589234 B2) in view of Dobak, III (US-5957963). Lalonde et al. disclose a heat transfer system comprising a hollow supply tube, injection tube 202, with a proximal end and a distal end, a tip member 203 positioned to surround the distal end of said tube 202 to create a cryo-chamber 205 therebetween, and a source of refrigerant fluid 103 connected in fluid communication with the proximal end of the supply tube 202 to introduce the refrigerant fluid into the supply tube for the transfer of the refrigerant fluid through said supply tube into said cryo-chamber 205 in a substantially liquid state for transition of the refrigerant fluid into gaseous state (column 6, lines 37-44) with a tip pressure and a tip temperature for heat transfer through said tip member 203 and into the gaseous fluid refrigerant in said cryo-chamber 205. Lalonde et al. fail to disclose a capillary tube in connection with said supply tube 202 wherein the diameter and length of said capillary tube is less than the diameter and length of said supply tube, wherein the aspect ratio of the diameter to length of said capillary tube is in

a range of 0.0008 to 0.0017, and wherein the length of said capillary tube is between 4.5 inches to 10 inches and the diameter of said capillary tube is between 0.008 inches and 0.010 inches, as required by claims 1-4 and 10-12. Dobak, III teaches a similar heat transfer system comprising a hollow supply tube 20 having a proximal and distal end and a capillary tube 22 having a proximal and distal end with the proximal of said capillary tube 22 connected in fluid communication with the distal end of said supply tube 20. Said supply tube 20 has a diameter of about 0.75 millimeters and a length of 70 to 100 centimeters (column 6, lines 25-32). Said capillary tube 22 has a diameter of about 0.25 millimeter (column 6, lines 49-51), which is about 0.0098 inch, and a length of 15 to 25 centimeters (column 6, lines 43-44), which is about 5.91 inches to 9.84 inches. Therefore the diameter and length of said capillary tube 22 are less than the diameter and length of said supply tube 20, the diameter to length aspect ratio of said capillary tube 22 is between the range of 0.0008 to 0.0017, the length of said capillary tube 22 is between 4.5 inches to 10 inches, and the diameter of said capillary tube 22 is between 0.008 inch to 0.010 inch. It would have been obvious to one of ordinary skill in the art to modify the heat transfer system disclosed by Lalonde et al. to include the supply and capillary tube arrangement taught by Dobak, III because said tube arrangement would aid in decreasing the pressure of the refrigerant and aid in the expansion of the refrigerant upon exiting said capillary tube which would result in greater cooling power and subsequent heat transfer.

13. Lalonde et al. further disclose that the refrigerant fluid may be nitrous oxide (column 4, lines 10-11), as required by claims 6 and 15, that the working pressure be

between 400 psia to 600 psia (column 5, lines 24-26) and therefore may be in a range between 350 psia and 500 psia, as required by claims 7 and 13, that the tip pressure may be about 12 psia (column 9, lines 8-9), which is less than one atmosphere, as required by claims 8 and 13, and that the tip temperature may be as low as –130 degrees C (column 7, lines 38-39) and therefore is less than –84 degrees C, as required by claims 9 and 14.

14. In addition to disclosing a heat transfer system, Lalonde et al. disclose a method of transferring heat which comprises the steps of providing a liquid refrigerant, which may be nitrous oxide (column 4, lines 10-11), at a first pressure, a working pressure between 400 psia to 600 psia (column 5, lines 24-26), and introducing said liquid refrigerant into a cryo-chamber 205 for transition of the liquid refrigerant into a gaseous state in said cryo-chamber 205, with an approximate pressure of 12 psia (column 9, lines 8-9), which is less than one atmosphere, to cause a transfer of heat outside said cryo-chamber 205 into the cryo-chamber 205 (see particularly column 6). The resulting tip temperature may be as low as –130 degrees C (column 7, lines 38-39). Lalonde et al. fail to disclose the step of reducing the pressure on the liquid refrigerant prior to the step of introducing the liquid refrigerant into said cryo-chamber 205, whereby said pressure reducing step comprises advancing the liquid refrigerant through a capillary tube with a lumen of length between 4.5 inches and 10 inches, a diameter between 0.008 inch to 0.010 inch, and having as aspect ratio of diameter to length being in a range of 0.0008 to 0.0017. Dobak, III teaches a similar heat transfer method using a hollow supply tube 20 having a proximal and distal end and a capillary tube 22 having a

proximal and distal end with the proximal of said capillary tube 22 connected in fluid communication with the distal end of said supply tube 20. Said supply tube 20 has a diameter of about 0.75 millimeters and a length of 70 to 100 centimeters (column 6, lines 25-32). Said capillary tube 22 has a diameter of about 0.25 millimeter (column 6, lines 49-51), which is about 0.0098 inch, and a length of 15 to 25 centimeters (column 6, lines 43-44), which is about 5.91 inches to 9.84 inches. Therefore the diameter and length of said capillary tube 22 are less than the diameter and length of said supply tube 20, the diameter to length aspect ratio of said capillary tube 22 is between the range of 0.0008 to 0.0017, the length of said capillary tube 22 is between 4.5 inches to 10 inches, and the diameter of said capillary tube 22 is between 0.008 inch to 0.010 inch. It would have been obvious to one of ordinary skill in the art to modify the heat transfer method disclosed by Lalonde et al. to include the supply and capillary tube arrangement taught by Dobak, III because said tube arrangement would aid in decreasing the pressure of the refrigerant and aid in the expansion of the refrigerant upon exiting said capillary tube which would result in greater cooling power and subsequent heat transfer. It should be understood that the combination of Lalonde et al. and Dobak, III meets the limitations set forth in method claims 16-20.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

> US-5423807 Milder 06-13-1995: discloses a cryogenic ablation catheter that may use nitrous oxide as a refrigerant, the refrigerant flowing through a first supply tube followed by a second tube of smaller dimensions and into a cryo-chamber.

US-5520682 Baust et al. 05-28-1996: discloses a surgical cryoprobe system and method capable of achieving temperatures below –196 degrees C that comprises flowing a liquid cryogenic refrigerant through a first supply tube followed by a second tube of smaller dimensions and involves the vaporization of the liquid cryogenic refrigerant.

US-5573532 Chang et al. 11-12-1996: discloses a cryogenic surgical instrument comprising a first supply tube followed by a second tube of smaller dimensions through which flows cryogenic refrigerant to cool the tip of said instrument.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard L. Leung whose telephone number is 703-306-4154. The examiner can normally be reached on Mon-Fri.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Denise L. Esquivel can be reached on 703-308-2597. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard L. Leung
Examiner
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rll

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